510(k) Summary

PREPARED: May 3, 2013

510(k) SPONSOR:
ICONACY Orthopedic Implants, LLC
4130 Corridor Drive
Warsaw, IN 46582

AUG 09 2013

CONTACT PERSON:
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TRADE NAME: **ICONACY™ I-Hip™ System**

COMMON NAMES: Total Hip System

CLASSIFICATION and CLASS: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR Section 888.3358, Class II)

PRODUCT CODE: LPH

PREDICATE DEVICE: ICONACY I-Hip Total Hip System, K121034

DEVICE DESCRIPTION: The ICONACY I-Hip consists of a collarless, tapered, forged titanium alloy femoral stem mated to a cobalt chrome alloy modular femoral head. This femoral construct articulates with an acetabular device assembly. The acetabular device assembly consists of a hemispherical titanium alloy cup coupled with a highly cross linked ultra-high molecular weight polyethylene (HXL-UHMWPE) liner. Forty percent of the femoral stem is circumferentially coated with a titanium coating designed to attain a cementless, press-fit fixation. The acetabular cup is machined from forged Ti-6Al-4V ELI alloy. The cup has a threaded polar hole for insertion. The outer hemispheric surface of the cup has a titanium plasma spray coating for cementless, press-fit fixation. A titanium locking ring is fixed into a groove on the cup to engage a groove on the HXL-UHMWPE liner. Standard instrumentation is used to implant the device.

The current submission is for modifications to the acetabular cups and locking rings cleared in K121034, and the addition of spiked and finned acetabular cups in the same sizes and materials as those cleared in K120134. The compatible femoral stems, femoral heads, acetabular liners and bone screws are unchanged from those cleared in K121034.

INDICATIONS FOR USE: The ICONACY I-Hip System is indicated for the following conditions: (1) a severely painful and/or disabled hip joint as a result of osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia, (2) avascular necrosis of the femoral head, (3) acute traumatic fracture of the femoral head or neck, (4) failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement, (5) certain cases of ankylosis, (6) nonunions, correction of functional deformity, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The ICONACY I-Hip System consists of femoral stem and acetabular cup (i.e. shell) porous coated components intended for cementless, press-fit fixation.

BASIS FOR SUBSTANTIAL EQUIVALENCE: The modified and additional components of the ICONACY I-Hip Total Hip System are substantially equivalent to the acetabular cups and locking rings cleared in K121034 based on similarities in design, materials, function and indications for use.

PERFORMANCE DATA: The described modifications are not expected to affect the performance of the I-Hip Total Hip System. A risk analysis of the modifications was completed and push-out, lever-out and torque-out testing of the modified designs was performed. Based on similarities in design, sizes, materials, function, indications for use and the results of this testing, the modified designs were determined to be substantially equivalent to the previous designs.

CLINICAL TESTING: Clinical testing was not required for determining substantial equivalence with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 9, 2013

Mr. Marc E. Ruhling
Director of Development, Hips & Shoulders
ICONACY Orthopedic Implants, LLC.
4130 Corridor Drive
Warsaw, Indiana 46582

Re: K131279
Trade/Device Name: Iconacy I-Hip Total Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: June 25, 2013
Received: June 26, 2013

Dear Mr. Ruhling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131279

Device Name: Iconacy I-Hip Total Hip System

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices